

## Michele M. Simkin

### Partner

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Michele M. Simkin provides strategic business counseling to life sciences, pharmaceutical, and medical device clients relating to all aspects of intellectual property, including patent procurement and portfolio management, licensing agreements, due diligence related to IP acquisitions or sales, as well as validity, non-infringement, and freedom to operate analyses. She has particular expertise in developing and executing intellectual property strategies for companion diagnostics, including claim drafting and portfolio structuring to support regulatory approval pathways, market access, and lifecycle management, as well as strategies designed to extend and enhance product exclusivity. Michele also advises clients on intellectual property issues arising from the use of artificial intelligence and machine learning in drug discovery and development, including protection of AI-enabled inventions, data-driven innovation, and related freedom-to-operate considerations. She is a partner in the firm's Chemical, Biotechnology & Pharmaceutical Practice. She previously served as chair of the firm's Intellectual Property Department, overseeing a team of over 300 IP professionals, and she is currently a member of the firm's Management Committee.

Michele represents a diverse range of clients, including pharmaceutical and biotechnology companies such as Alkermes Pharmaceuticals, 10x Genomics, Inc., and Celgene Corporation (now part of Bristol Myers Squibb), mid-sized biotechnology companies such as MacroGenics, Inc. and EnGenelC Ltd., manufacturing companies such as Stoner, Inc. (maker of Invisible Glass products), universities such as the University of Pittsburgh, and start-up ventures in both traditional pharmaceuticals and biotechnology applications, including Enterin, Inc. and BlueWillow Biologics, Inc.

Michele began her patent career in 1988 as a patent examiner in the biotechnology group of the U.S. Patent and Trademark Office. As an undergraduate, she worked in the laboratory of Professor David L. Nelson, culturing and harvesting the protozoan *Paramecium*, which was used as a model system to study signal transduction using biochemical, genetic, molecular genetic, cell biological, and electrophysiological tools.

### Representative Experience

- Representation of EnGeneIC in obtaining over 30 U.S. patents and 200 patents worldwide, with the claimed technology encompassing products in clinical trials for treating Glioblastoma Multiforme (GBM), malignant pleural mesothelioma, non-small cell lung cancer, and recurrent/refractory solid or CNS tumors. The novel EDV nanocell technology is a first-in-class cyto-immunotherapy platform targeting cancer tumors directly as well as leveraging the patient's own immune system for improved efficacy and outcome.
- Representation of Enterin, Inc. in obtaining multiple U.S. and international patents, covering both products and methods of treatment, directed to aminosterol compounds useful in treating neurodegenerative diseases such as Parkinson's Disease. Enterin's lead molecule, ENT-01, recently met its primary endpoint in a Phase 2b study for patients with Parkinson's Disease.
- Representation of MacroGenics in obtaining U.S. and international patent protection for Retifanlimab, which is an investigational, humanized, proprietary anti-PD-1 monoclonal antibody being developed for use as monotherapy as well as in combination with other potential cancer therapeutics.

## Awards and Recognition

- Selected by her peers for inclusion in *The Best Lawyers in America*® in the field of Biotechnology and Life Sciences Practice (2008-2024)
- *Recognized in IAM Patent 1000 – The World's Leading Patent Practitioners* for her work in patent prosecution (2020-2024)
- Recognized by Leaders League Intelligence Report & Rankings, as a Top Tiered Leading Practitioner for Patent Prosecution, and in Best Law Firm for Patent Prosecution: (2021, 2022)

## Affiliations

- American Bar Association

## Presentations and Publications

- Author, "GLP-1 Receptor Agonists: The Surge of M&A Activity and the Future of Metabolic Health," *Health Care Law Today* (June 3, 2025)
- Author, "Cancer Drugs: Deals and Licensing for Antibody-Drug Conjugates," *Health Care Law Today* (June 5, 2024)
- Lectured on and has authored a number of articles on intellectual property topics.

## Sectors

- [Cannabis](#)
- [Health Care & Life Sciences](#)
- [Pharmaceuticals](#)

## Practice Areas

- [Chemical, Biotechnology & Pharmaceutical](#)
- [IP Due Diligence](#)

- [Intellectual Property](#)

## **Education**

- The George Washington University National Law Center (J.D., 1993)
- University of Wisconsin-Madison (B.S., 1988)
  - Biochemistry
  - Molecular Biology

## **Admissions**

- U.S. Patent and Trademark Office
- District of Columbia
- U.S. Court of Appeals for the Federal Circuit
- District Court for the District of Columbia